

11.03 GLYCOMACROPEPTIDE AND ESSENTIAL AMINO ACIDS WITH VITAMINS AND MINERALS

Oral liquid 250 mL, 30 (Tylactin RTD)

Tylactin® RTD

Cortex Health Pty Ltd

1 Purpose of Submission

- 1.1 The Committee Secretariat submission requested that glycomacropeptide and essential amino acids with vitamins and minerals (Tylactin® RTD) new formulation continue to be listed on the Pharmaceutical Benefits Scheme (PBS) under the existing conditions.

2 Background

- 2.1 Tylactin RTD was recommended by the PBAC at its July 2015 meeting and is currently listed on the PBS as a restricted benefit for the treatment of tyrosinaemia (TYR).
- 2.2 The submissions claimed the new formulation of Tylactin RTD continues to meet the requirements for foods that have special medical purposes as set out under the *Australia New Zealand Food Standards Code – Standard 2.9.5: Food for Special Medical Purposes*.
- 2.3 As Tylactin RTD is marketed as a nutritional product and not a therapeutic good, it is not registered in the Australian Register of Therapeutic Goods.

3 Requested listing

- 3.1 The submission requested no restriction changes to the existing listings.

4 Consideration of the evidence

Sponsor hearing

- 4.1 There was no hearing for this item.

Consumer comments

- 4.2 The PBAC noted that no consumer comments were received for this item.

Nutritional Profile

- 4.3 The nutritional profile comparison of Tylactin RTD's new and previous formulations is presented in Table 1.

Table 1: Tylactin RTD reformulation nutritional profile comparison

Nutrient	Product nutritional content (per 250 mL carton)		
	Tylactin RTD 15 new formulation	Tylactin RTD 15 current formulation	New formula / current formula nutritional content
Protein (g)	15	15	100%
Energy kcals	198	200	99%
Total Fat (g)	5.3	5	106%
Saturated fat (g)	1	2	50%
Cholesterol (mg)	0.2	0	-
DHA (mg)	75	0	-
Total Carbohydrate (g)	24	24	100%
Dietary fibre (g)	2.1	1	210%
Total sugar (g)	4.9	19	26%
Added sugar (g)	4	19	21%
Vitamins & Minerals			
Riboflavin (mg)	0.4	0.4	100%
Niacin (mg)	12.0	5.0	240%
Vitamin B6 (mg)	0.5	0.4	125%
Vitamin B12 (mcg)	0.9	0.8	113%
Biotin (mcg)	8	8	100%
Pantothenic acid (mg)	2	1.8	111%
Vitamin A (mcg retinol equivalents)	272	270	100%
Vitamin D (mcg of cholecalciferol)	7	6.25	112%
Vitamin E (mg a-tocopherol equivalents)	3	3.35	90%
Vitamin K (mcg)	30	30	100%
Vitamin K1 (mcg)	15	30	50%
Vitamin K2 (MK-7) (mcg)	15	0	-
Thiamin (mg)	0.4	0.4	100%
Vitamin C (mg)	28	28	100%
Folate, DFE (mcg)	140	238	59%
Folic acid (mcg)	82	140	59%
Choline (mg)	205	206	100%
Sodium (mg)	306	300	102%
Calcium (mg)	367	350	104%
Phosphorous (mg)	300	315	95%
Magnesium (mg)	78	120	65%
Potassium (mg)	408	340	121%
Iron (mg)	4.5	4.5	100%
Copper (mg)	0.2	0.2	100%
Zinc (mg)	3.0	3.3	91%
Manganese (mg)	0.8	0.8	100%
Iodine (mcg)	60	57	105%
Molybdenum (mcg)	15	15	100%
Selenium (mcg)	20	20	100%
Chromium (mcg)	13	13	100%
Amino acids			
Aspartic acid (g)	0.62	1	62%

Nutrient	Product nutritional content (per 250 mL carton)		
	Tylactin RTD 15 new formulation	Tylactin RTD 15 current formulation	New formula / current formula nutritional content
Leucine (g)	2.25	3	75%
Glutamine (g)	1.5	2.25	67%
Lysine (g)	0.435	0.818	53%
Valine (g)	0.68	0.9	76%
Isoleucine (g)	0.79	1.3	61%
Arginine (g)	1.65	1.593	104%
Glycine (g)	1.5	0.148	1014%
Proline (g)	0.87	1.14	76%
Phenylalanine (g)	0.015	0.025	60%
Tyrosine (g)	0.0075	0.003	250%
Serine (g)	0.49	0.8	61%
Threonine (g)	1.23	2.2	56%
Histidine (g)	0.45	0.361	125%
Alanine (g)	0.465	0.7	66%
Cystine (g)	0.165	0.162	102%
Tryptophan (g)	0.38	0.219	174%
Taurine (mg)	0	30	0%
Methionine (g)	0.135	0.18	75%

Source: submission main body p4

AI: average intake; DFE: dietary folate equivalent; DHA: Docosahexaenoic Acid; GMP: glycomacropeptide; NRV: nutrient reference values; Phe: phenylalanine; RDI: recommended daily intake

4.4 The submission stated that the reformulations:

- improve the purity of the glycomacropeptide and thereby reduce the tyrosine and phenylalanine content.
- improve the nutrient profile of several nutrients, aiming to best meet RDI requirements across age groups.
- unify the vitamin and mineral blends used across products to improve productivity (e.g., reduce downtime when a manufacturing line switches between making PKU Glytactin RTD and Tylactin RTD).
- increase reliability of supply by allowing the sponsor to more quickly fill orders when the global formulas are used.

4.5 The PBAC advised that the new formulation is expected to provide a non-inferior clinical benefit for the management of TYR in comparison to the current formulation.

Estimated PBS usage and financial implications

4.6 The submission did not present economic or financial evaluations. The submission requested no change to the current pricing arrangements.

4.7 The submission considered the formulation changes will have nil financial impact to Government as no change in price is requested and it did not estimate any change in utilisation would occur.

For more detail on PBAC's view, see section 6 PBAC outcome.

5 NPWP consideration

- 5.1 The Nutritional Products Working Party (NPWP) advised that the new formulation is expected to provide non-inferior clinical benefit for the treatment of tyrosinaemia.
- 5.2 The NPWP supported the new formulation of Tylactin RTD continuing to be listed on the PBS under the existing conditions as the existing formulation.

For more detail on PBAC's view, see section 6 PBAC outcome.

6 PBAC Outcome

- 6.1 The PBAC recommended that new formulation of glycomacropeptide and essential amino acids with vitamins and minerals (Tylactin® RTD) continue to be listed on the PBS under the existing conditions of the current formulation.
- 6.2 The PBAC noted and supported the NPWP advice that the new formulation is expected to provide a non-inferior clinical benefit for the management of TYR.
- 6.3 The PBAC noted there were no changes requested to the circumstances under which the existing listings are available.
- 6.4 The PBAC considered the formulation changes would not affect utilisation or the cost to Government.
- 6.5 The PBAC noted that this submission is not eligible for an Independent Review as it received a positive recommendation.

Outcome:

Recommended

7 Recommended listing

- 7.1 No change to the existing listing.

8 Context for Decision

The PBAC helps decide whether and, if so, how medicines should be subsidised through the Pharmaceutical Benefits Scheme (PBS) in Australia. It considers applications regarding the listing of medicines on the PBS and provides advice about other matters relating to the operation of the PBS in this context. A PBAC decision in relation to PBS listings does not necessarily represent a final PBAC view about the merits of the medicine or the circumstances in which it should be made available through the PBS. The PBAC welcomes applications containing new information at any time.

9 Sponsor's Comment

The sponsor had no comment.